Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12609

0 - FRONT

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN

Page 1 of 1

Form Approved OMB No 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 72034 / 12609

A. Patient information

1 Patient identifier	2 Age at time of event: 28 or Date of birth [redacted]	3 Sex	4 Weight
In confidence		☒ female ☐ male	145 lbs or ____ kgs

B. Adverse event or product problem

1 ☒ Adverse event and/or ☐ Product problem (e g , defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☒ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other. ____

3. Date of event (mo/day/yr): Began late July '97

4 Date of this report (mo/day/yr): Oct 10, 1997

5 Describe event or problem – I was on a diet plan that was described as herbal. The first three ingredients were Maltvang (Ephedra) Guarana, Kola Nut etc. I was on the plan for approx. 8 months and early on developed thyroid nodules (3) Many biopsies conducted, all inconclusive so I was put on Synthroid to make me more on the hyperthyroid side to shrink nodules. Shortly thereafter I developed insomnia, anxiety, extreme weight loss - (after discontinuing products) 25 lbs in one month and was diagnosed with Severe panic disorder. I was hospitalized for 5 days and lost 5 weeks of work at a brand new job. The other ingredients in the diet plan, I later found out were mostly stimulants. Doctors believe it is quite possible that the diet brought on the nodules (and or panic disorder (Synthroid combined with diet may have set it off)

6 Relevant tests/laboratory data, including dates – There have been too many tests conduct to report in this small space. Among them were: thyroid tests, fine needle ultra sounded guided biopsies, several sets of bloodwork. Thyroid scan, EKG, Holter monitor, (for chest pain) echocardiogram. CAT SCAN, Abdominal ultrasound upper GI series. ETC – (Dates can be obtained plus other tests that I don't know name of)

7 Other relevant history, including preexisting medical conditions (e g , allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc) Before this all occured I was a smoker (less than one pack per day) and took orthocyclen for the treatment of endometriosis. No other pre-existing conditions. Panic attacks and extreme weight loss never occured before.

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)

#1 Consumer Direct Inc - "Direct Health" on label

#2 Body Tabs + MA, - no mgs Listed

2 Dose, frequency & route used

#1 3 tabs before each meal

#2 1 "MAX" power drink 1-2 times per day

3 Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 Nov (switched companies 4mo later)

#2 through early August 1997

4 Diagnosis for use (indication)

#1 Weight Loss

#2

5 Event abated after use stopped or dose reduced

#1 ☐ yes ☒ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)

#1

#2

7 Exp. date (if known)

#1 None

#2

8 Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)

– –

10 Concomitant medical products and therapy dates (exclude treatment of event)

Synthroid. Treated by endocrinologist since March 1997.

D. Suspect medical device

1 Brand name

2 Type of device

3 Manufacturer name & address

RECEIVED OCT 27 1997

4 Operator of device

- ☐ health professional
- ☐ lay user/patient
- ☐ other

5 Expiration date (mo/day/yr)

6

model # ____

catalog # REC'D.

serial # OCT 23 1997

lot # ____

other # MEDWATCH CTU

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)

☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. [redacted]

000001

2 Health professional? ☐ yes ☒ no

3 Occupation: Doctoral candidate (student) & research assistant.

4 Also reported to

- ☐ manufacturer
- ☒ user facility – some info, not all
- ☐ distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

U S. DEPARTMENT OF H[illegible]TH AND HUMAN SERVICES
Public[illegible]ith Service
FOOD AND DRUG ADMINISTRATION

COMPLAINT / INJURY REPORT

COMPLAINT NUMBER: NYK-3494

2. DATE OF COMPLAINT (Month / Day / Year): 5/20/98

3. FORM OF COMPLAINT
a.
(1) [X] TELEPHONE
(2) [ ] LETTER
(3) [ ] VISIT

4. SOURCE OF COMPLAINT
a.
(1) [X] CONSUMER (3) [ ] TRADE SOURCE
(2) [ ] GOVERNMENT (4) [ ] OTHER
[ ] L [ ] S [ ] F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include ZIP Code)
[redacted]

b. AREA CODE AND TELEPHONE NUMBER
HOME ([redacted]
WORK ( )

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT / INJURY
Possible adverse reaction after consuming Body Tabs and Max. Both products contain MaHuang. The adverse reactions include nodules on thyroid, insomnia, severe wäigth loss, and anxiety.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) [ ] NO (2) [X] YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO
(2) [X] YES *
*(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED
(1) [ ] NO
(2) [X] YES
DATE: 5/5/98

b. TYPE SYMPTOMS — ONSET (HR.)
(1) [ ] VOMITING
(2) [ ] NAUSEA
(3) [ ] DIARRHEA
(4) [ ] FEVER
(5) [ ] SKIN/EYE IRR.
(6) [ ] HEADACHE
(7) [X] OTHER see medical records

c. ATTENDING HEALTH PROFESSIONAL?
(1) [ ] NO (2) [X] YES
(If "Yes" give name, address, and phone number)
see medical records

d. HOSPITALIZATION REQUIRED?
(1) [ ] NO (2) [X] YES
(If "Yes" give name, address, phone number and dates)
[redacted]

8. PRODUCT AND LABELING
a. BRAND NAME: Body Tabs herbal Tabs see remarks
b. PRODUCT NAME: Herbal tabs see remarks
c. SIZE AND PACKAGE TYPE: 180 tabs Plastic bottle
d. NAME AND LOCATION OF STORE WHERE PURCHASED: Mail Order: Consumer Direct 3361 Boyington Dr. Carrollton, Texas 75006
e. PACKAGE CODE / SERIAL NUMBER / ETC.: unknown
EXP. / USE BY DATE:
f. DATE PURCHASED: 11/96
g. PRODUCT USED (If "Yes" enter date) (1) [ ] NO (2) [X] YES Date: 11/96-7/97
h. AMT. REMAINING: N/A

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: DAL-DO
b. C.F. NO.: nocf
c. NAME AND LOCATION OF FIRM (Include ZIP Code): Same as 8d.
d. IMPORT PRODUCT
(1) [X] NO
(2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEY WORD
(1) CODE: Rx
(2) DESCRIPTION: ThyroidNodules

b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [X] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

b. DISPOSITION
(1) [X] IMMEDIATE FOLLOW-UP
(2) [ ] F / U NEXT EI
(3) [ ] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) [ ] REFERRED TO OTHER FDA _____ DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 54YCC99

12. INFORMATION COPIES TO:
[ ] HFM-660 [ ] HFZ-343
[ ] HFD-730 [ ] HFC-161
[ ] HFV-210 [ ] HFS-635
[ ] OTHER _____

13. REMARKS: 8 cont Max dietary supplement beverage Mix;14.8 oz. powder in a plastic bottle
All original records to be sent to BUF-DO Joan Trankel

14. NAME AND TITLE OF DISPOSITION OFFICIAL: Thomas J. Mooney, Investigator

15. DATE: 5/20/98

FORM FDA 2516 (1/96)

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85

★ U S GPO 1997-521-557/85348

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: NYK-3494

2.a. ACTION REQUESTED
(1) ☒ INVESTIGATION
(2) ☐ COLLECT SAMPLE
(3) ☐ INSPECTION
(4) ☐ OTHER:

2.b. REMARKS *(Additional details)*

2.c. REQUESTING OFFICIAL'S NAME AND TITLE: Otto D. Vitillo, SCSO

2.d. DATE REQUESTED: 5/20/98

2.e. PRODUCT NAME: Body Tabs/ Max

3.a. ASSIGNED TO: T. Mooney

3.b. DUE BY: 5/21/98

4.a. ACTION TAKEN
(1) ☒ INVESTIGATION
(2) ☐ SAMPLE COLLECTED
(3) ☐ INSPECTION
(4) ☐ NONE

4.b. SAMPLE NUMBER(s)

4.c. DESCRIPTION OF ACTION TAKEN

On 5/21/98 I presented my credentials to [redacted]. Ms. [redacted] signed the the authorization for medical records disclosure form which will be forwarded to BUF-DO. Ms [redacted] stated that all medical treatment was conducted in the [redacted] area. Ms. [redacted] stated that she developed nodules on her thyroid while taking body tabs herbal tablets and MAX dietary supplement. Ms. [redacted] stated that while taking these products she also experienced insomia, severe weight loss and anxiety. Ms. [redacted] stated that she first started taking these products in November, 1996 and begun experiencing side effects in July, 1997. Ms. [redacted] stated that from 11/96 until 2/97 she was consuming these products from another distributor, but could not remember their name. From 2/97-7/97 these products were purchased from Consumer Direct Carrollton, Texas. Ms. [redacted] stated that both these products contain MaHuang. Ms. [redacted] stated that she stopped taking these products in July, 1997 but still experienced side effects for the next eight weeks. Ms. [redacted] stated she underwent numerous test including blood,EKG, heart monitor for chest pain, abdominal ultra sound,CAT Scan and upper GI series testing. Ms. [redacted] was prescribed Synthroid for the treatment of the thyroid nodules. Ms. [redacted] stated that she was diagnosed with severe panic disorder. Ms. [redacted] stated that she never had any of these conditions prior to consuming these products. Ms. [redacted] would not provide me with the original product labeling. A poor copy of the product labeling was obtained. The label of these products has a dark green background with black lettering.

4.d. ACTION OFFICIAL'S NAME AND TITLE: Thomas J. Mooney Investigator

4.e. ACTION DISTRICT: NYK-DO

4.f. DATE COMPLETED: 5/21/98

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

5.a. HOME DIST.: DAL-DO

5.b. CF NO.: nocf

5.c. NAME AND ADDRESS: Consumer Direct
3361 Boyington Dr.
Carrollton, Texas 75006

6. PROGRAM DATA

6.a. OPERATION	6.b. PAC	6.c. PRODUCT CODE	
13	03R801	54YCC99	
6.d EMP. HOME DIST.	**6.e. EMP. NO.**	**6.f. POS CL.**	**6.g. HOURS**
NYK-DO	888	2	6

7. EVALUATION
(0) ☒ PENDING
(1) ☐ NO ACTION INDICATED (NAI)
(2) ☐ VOLUNTARY ACTION INDICATED (VAI)
(3) ☐ OFFICIAL ACTION INDICATED (OAI)
(4) ☐ NOT AN FDA OBLIGATION
(5) ☐ REFERRED TO HOME DISTRICT
(6) ☐ INSUFFICIENT INFO. UNABLE TO EVAL.
(7) ☐ REFERRED TO OCI

8. FINAL DISPOSITION
(1) ☐ FOLLOW-UP NEXT E1
(2) ☐ WARNING LETTER
(3) ☐ CITATION
(4) ☐ SEIZURE
(5) ☐ INJUNCTION / PROSECUTION
(6) ☐ REFERRED TO OTHER AGENCY
(Indicate Agency in **Remarks***)*
(7) ☐ RECALL
(8) ☐ NO ACTION

9. INFO. COPIES TO:
☐ HFB-100
☐ HFD-730
☐ HFV-236
☐ HFZ-343
☐ HFC-161
☐ HFS-635
☐ _____
☐ _____
☐ _____
☐ _____
☐ _____
☐ _____
☐ _____

REMARKS

This follow-up was conducted as per NYK-DO assignment #10630 and from a request from CFSAN as per assignment number 98-832.

000004

NAME AND TITLE OF DISPOSITION OFFICIAL	DISPOSITION	DISPOSITION DATE

FORM FDA 2516a (3/94)

★ U.S GPO. 1995-386-960/20706

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: NYK-3493

2. ACTION REQUESTED
(1) ☐ INVESTIGATION
(2) ☐ COLLECT SAMPLE
(3) ☐ INSPECTION
(4) ☒ OTHER

(a) REMARKS *(Additional details)*
Collect medical records per assignment from CFSAN, Project #12609 and f/u to NYK-3494

(b) REQUESTING OFFICIAL'S NAME AND TITLE	(c) DATE REQUESTED	(d) PRODUCT NAME
Joan B. Trankle, R & E Coordinator	6/5/98	Body Tabs/Max

3. ASSIGNED TO:	(a) DUE BY	4. ACTION TAKEN	(a) SAMPLE NUMBER(s)
Denise L. Terzian	ASAP	(1) ☐ INVESTIGATION (2) ☐ SAMPLE COLLECTED (3) ☐ INSPECTION (4) ☒ Collect records	NONE

(b) DESCRIPTION OF ACTION TAKEN

On 6/5/98, as a follow-up to an assignment from CFSAN, Division of Enforcement and Programs, HFS-636, under Project #12609, I visited the following doctors and hospitals and presented their staff with an Authorization for Medical Records Disclosure form from [redacted] I faxed a copy of the Authorization to the following facilities: Dr. [redacted] I called and spoke to Dr. [redacted] and met with her on 6/8/98 and received copies of the records at that time. Between 6/5/98 and 6/25/98, I received copies of the medical records from all of the doctors and hospitals listed.

NOTE: Prior to visiting these facilities, I telephoned [redacted] and asked her for the list list of doctors and hospitals she had visited during the time period listed. The health care provider's name, address and phone numbers were not listed on the Adverse Event Questionnaire completed by Investigator Thomas Mooney. I have attached an Addendum to the questionnaire listing the names of the doctor's and hospitals and the time periods in which they were visited.

ATTACHED: 1. Dr. [redacted] records 2. Dr. [redacted] records 3. [redacted]
4. Dr. [redacted] records 5. Dr. [redacted] records 6. [redacted] Hospital
7. [redacted] 8. Dr. [redacted] records 9. [redacted]

(c) ACTION OFFICIAL'S NAME AND TITLE	(d) ACTION DISTRICT	(e) DATE COMPLETED
Denise L. Terzian, Investigator Denise L. Terzian	BUF	6/25/98

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

(a) HOME DIST.	(C) NAME AND ADDRESS	(b). CF NO.
DAL-DO	Consumer Direct 3361 Boyington Dr. Carrollton, TX 75006	NO CFN

6. PROGRAM DATA

(a) OPERATION	(b) PAC	(c) PRODUCT CODE	(d) EMP. HOME DIST.	(e) EMP. NO.	(f) POS CL.	(g) HOURS
13	03R801	54Ycc99	BUF-DO	283	2	~~10~~ 13

7. EVALUATION
(0) ☒ PENDING
(1) ☐ NO ACTION INDICATED (NAI)
(2) ☐ VOLUNTARY ACTION INDICATED (VAI)
(3) ☐ OFFICIAL ACTION INDICATED (OAI)
(4) ☐ NOT AN FDA OBLIGATION
(5) ☒ REFERRED TO HOME DISTRICT
(6) ☐ INSUFFICIENT INFO. UNABLE TO EVAL.

8. FINAL DISPOSITION
(1) ☐ FOLLOW-UP NEXT E I
(2) ☐ WARNING LETTER
(3) ☐ CITATION
(4) ☐ SEIZURE
(5) ☐ INJUNCTION/PROSECUTION
(6) ☐ REFERRED TO OTHER AGENCY *(Indicate Agency in Remarks)*
(7) ☐ RECALL
(8) ☐ NO ACTION

9. INFO. COPIES TO
☐ HFB-100
☐ HFD-333
☐ HFD-730
☐ HFV-236
☐ HFZ-343
☐ HFC-161
☐ _____
_____

REMARKS

000005

NAME AND TITLE OF DISPOSITION OFFICIAL	DISPOSITION	DISPOSITION DATE

FORM FDA 2516a (6/89)

Adverse Event Questionnaire

Complaint Number: NYK-3494 **Investigator:** Thomas J. Mooney

Consumer Information

Date of Report: 05/20/98 (MM/DD/YY)

Initial Report Source: ☐ORA Consumer Injury ☐Telephone ☐Correspondence ☒MedWatch ☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☒F ☐M Age: 29

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic ☐8-Other_____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 7/97
Previous Adverse Effects to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Home

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
see attached

How long did the symptoms last?
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.).
see attached

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☒No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number:

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist ☐Other (specify) _____

What medical tests were performed and what were the results?

What was the medical diagnosis?
What treatment(s) was given (e.g., drugs, other)?
see attached

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☒No

000006

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSH HFS-452
98 JUL -9 A11:25

Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

Other Product Problems

2. ☐Foreign Object
(specify): N/A

3. ☐Other (specify):
N/A

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

see attached

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown

~~Body Tabs~~

MaHuang Extract, Guarana Extract, Kola Nut extract, ~~Ginger Root Powder, White Willow~~ Taurine, l, phenyalanine MAY-I-phenylalanine

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☐Other_____
☒Unknown

☐Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐Yes ☒No ☐Unknown Product Sample Available: ☐Yes ☐No ☐Unknown
see attached for labeling

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☐Yes ☒No

Hospitalization: ☐Yes ☐No (if YES, indicate if initial or prolonged) 5 days

Required intervention to prevent permanent impairment/damage: ☒Yes ☐No

Did the adverse event result in a congenital anomaly: ☐Yes ☒No

000007

ADVERSE EVENT QUESTIONNAIRE

INFORMATION ON ADVERSE EVENT

DESCRIBE THE ADVERSE EVENT (INCLUDING SYMPTOMS AND THE TIME LAPSE FROM USING PRODUCT TO ONSET OF SYMPTOMS)

Ms. [redacted] began using these products in November, 1996. In March, 1997, Ms [redacted] was treated for nodules on her thyroid. Ms. [redacted] was prescribed synthroid by her physician for the treatment of these nodules. Ms. [redacted] stated that she never had any problems with her thyroid prior to this incident. Ms. [redacted] lost 25 pound in June, 1997 and during this time period experienced Insomnia, anxiety, and anorexia. Ms. [redacted] stopped using these products in July, 1997.

HOW LONG DID THE SYMPTOMS LAST:

The symptoms lasted from July, 1997 to September, 1997. Ms. [redacted] stopped taking these products in July, 1997 and the symptoms lasted approximately eight weeks after she stopped using taking these products.

Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken).

Ms. [redacted] stated that she took the body tabs herbal tablets, 2 tablets after every meal for a total of 6 tablets a day and max dietary supplement beverage mix (1 tablespoon 1 to 2 times per day. These products were consumed from 11/96 through 7/97).

LIST ALL MEDICATIONS, DIETARY SUPPLEMENTS, FOODS AND OTHER PRODUCTS USED AT THE TIME OF THE EVENT:

Ms. [redacted] was prescribed Synthroid for the treatment of thyroid nodules. Ms. [redacted] took body tabs, max drink, and low fat foods.

MEDICAL INFORMATION:

WHAT MEDICAL TEST WERE PERFORMED AND WHAT WERE THE RESULTS:

Medical Tests include blood test, EKG, Heart Monitor for chest pain, abdominal ultra sound, CAT Scan and upper GI series. All tests were normal.

WHAT WAS THE MEDICAL DIAGNOSIS:

Severe Panic Disorder

WHAT TREATMENT WAS GIVEN:

The only treatment given was Synthroid for the thyroid nodules.

ATTACHMENTS

1. MAX LABELING TYPED
2. BODY TAB LABELING TYPED
3. XEROX OF MAX LABELING
4. XEROX OF BODY TABS LABELING
5. MEDICAL RELEASE
6. ADVERSE EVENT QUESTIONAIRE.

ORIG AND EX: BUF-DO Joan Trankel
cc and ex: NYK-DO Complaint Coordinator
cc and ex: LI-RP:

ADDENDUM TO ADVERSE EVENT QUESTIONNAIRE CFSAN PROJECT #12609 AND NYK-3494

On 6/5/98 I telephoned [redacted] and asked her for a list of doctors and hospitals she had visited during this time period, since the health care provider's name, address and phone numbers were not listed on the Adverse Event Questionnaire completed.

Ms. [redacted] stated she visited the following doctors during the periods listed:

[redacted] March 1997

[redacted] March-April 1997

[redacted] March 1997

[redacted] April 1997

[redacted] Summer 1997

[redacted] July-August 1997

[redacted]

August 1997 (2 visits)

[redacted]

September 1997 (admitted)

[redacted]

Late Summer/Fall 1997 (referred to by Dr. [redacted]

dlt

Denise L. Terzian
Investigator
BUF-DO/ALB-RP

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
Olympic Towers, Suite 100
300 Pearl Street
Buffalo, NY 14202

DATE: July 2, 1998

TO: Bridgette Wallace, ARM Monitor
CFSAN, HFS-636

FROM: Joan Trankle, BUF/NYK District
Upstate New York

SUBJECT: CFSAN PROJECT #12609

Attached are the documents requested in CFSAN memo dated May 5, 1998. Delays in completing this assignment were due a change of address of the consumer, requiring follow up by Downstate Investigators, and delays by medical facilities in filling our requests for medical records.

Joan Trankle

Joan Trankle

Attachments

- CFSAN assignment
- FD-2516/2516a - NYK-3493
- Adverse Event Questionnaire
- photocopies of labeling
- medical records